03/25/24 BIG PHARMA

Scientists Caution About CDC Guidance on Over-the-Counter Drugs for COVID + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

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Scientists Caution About CDC Guidance on Over-the-Counter Drugs for COVID

CIDRAP reported:

In its most recent guidelines on the use of over-the-counter (OTC) drugs for COVID-19, the U.S. Centers for Disease Control and Prevention (CDC) says that mildly ill patients can relieve symptoms such as fever and sore throat with acetaminophen or ibuprofen, but a team led by Florida Atlantic University (FAU) researchers says it's not that simple.

In a review in the American Journal of Medicine, the investigators conclude that the decision to take acetaminophen (eg, Tylenol), aspirin, or ibuprofen (eg, Motrin, Advil) should be done on an individual basis under the guidance of a clinician.

This is because the drugs aren't risk-free, with overuse of acetaminophen tied to irreversible liver damage, liver failure, the need for liver transplant, and kidney damage, the authors noted. While aspirin's anti-inflammatory properties may be useful in treating moderate to severe COVID-19, it carries the risk of bleeding, especially in the gastrointestinal (GI) tract. This is of particular concern in COVID-19, which may itself lead to bleeding and clotting abnormalities.

Compared with aspirin, ibuprofen, naproxen (eg, Aleve), and other non-steroidal anti-inflammatory drugs (NSAIDs) have greater adverse-event profiles, namely for gastroenteritis (inflammation of the GI tract) and peptic ulcers. As with acetaminophen, long-term use of these drugs can lead to liver and kidney toxicity.

BioNTech Gets U.S. Agency Notice Over Default on COVID Vaccine Royalties

Reuters reported:

BioNTech (22UAy.DE) said on Monday the U.S. National Institutes of Health has sent a notice to the German company regarding default on the payment of royalties and other payments related to its COVID-19 vaccine.

BioNTech, which partnered with U.S.-pharma giant Pfizer (PFE.N) for its COVID-19 vaccine, however, said it disagreed with the positions being taken by the NIH and intends to defend against all allegations of breach.

BioNTech has taken the license for certain patents from the NIH, among other entities, due to which the U.S. government is owed certain royalty payments, according to the German company's annual report.

The German government had granted BioNTech 375 million euros ($445 million) for its COVID-19 vaccine development program in September 2020.

EDA Settles Lawsuit Over Ivermectin Social Media Posts

Newsweek reported:

The FDA has agreed to delete and never republish several social media posts suggesting that ivermectin, a drug that some doctors used to treat COVID-19, is for animals and not humans.

While the FDA still does not approve of using ivermectin to treat COVID, it settled Thursday a lawsuit brought by three doctors who sued it, as well as the Department of Health and Human Services and its secretary, Xavier Becerra, and FDA secretary Robert Califf. All parties have settled.

The lawsuit, filed on June 2, 2022, was brought by doctors Mary Talley Bowden, Paul Marik and Robert Apter, each of whom claimed the FDA was interfering with their ability to practice medicine. The case was initially dismissed on the grounds the FDA had "sovereign immunity," although a U.S. Court of Appeals for the Fifth Circuit reversed the lower court's decision saying that the "FDA is not a physician."

The FDA and the doctors reached a settlement dated Thursday that stipulates the FDA will retire a Consumer update titled, "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." The FDA also will delete and not republish posts to Twitter (now X), LinkedIn and Facebook that read: "You are not a horse. Your are not a cow. Seriously, y'all. Stop it."

This issue was famously brought to the forefront when podcaster Joe Rogan grilled CNN chief medical correspondent Sanjay Gupta over the former's use of ivermectin, which CNN repeatedly referred to as a "horse dewormer."

Amgen Wants in on the Booming Weight Loss Drug Market — and It's Taking a Different Approach

CNBC reported:

Amgen is taking a new approach as it tries to stand out in a crowded field of drugmakers racing to develop the next blockbuster weight loss drug.

The biotech company is testing an injectable treatment that helps people lose weight differently from the existing injections from Novo Nordisk and Eli Lilly, and other obesity medicines in development. The experimental, called MariTide, also appears to help patients keep weight off after they stop taking it.

The drugmaker is also testing its drug to be taken once a month or even less frequently, which could offer more convenience than the weekly medicines on the market.

It's too early to say how competitive Amgen will be in the budding weight loss drug space, which Novo Nordisk and Eli Lilly have so far dominated.

The World's Most Expensive Drug Is Now a $4.25 Million Gene Therapy

TIME reported:

A new gene therapy for an ultra-rare disease will have a wholesale cost of $4.25 million, making it the world's most expensive drug.

The one-time treatment, Lenmeldy, won U.S. regulatory approval on Monday to correct the underlying cause of a hereditary condition called early-onset metachromatic leukodystrophy, or MLD.

MLD is a fatal disease in which infants sometimes start to lose the ability to walk and talk. Orchard Therapeutics said the drug's price "reflects its clinical, economic and societal value" in a statement Wednesday.

The drug's cost tops that of CSL Behring LLC's Hemgenix, a one-time infusion for hemophilia priced at $3.5 million.

What's Driving Big Pharma's Recent Market Performance?

Forbes reported:

The financial performance of major pharmaceutical companies highlights the divergent trajectories of success of GLP-1 manufacturers and the weakness caused by diminishing COVID-19 sales.

Eli Lilly and Novo Nordisk have delivered strong returns, driven by their advances in the obesity-drug market. In contrast, Pfizer has encountered setbacks, losing its fourth position among the top 20 Big Pharma entities. Notably, Moderna has exited this elite group altogether, indicative of its diminished market standing.

The primary driver of growth in the sector last year was the exceptional performance of GLP-1 drugs from Eli Lilly and Novo Nordisk. Eli Lilly emerged as the industry leader, surpassing J&J for the first time. The company experienced an 11% year-over-year decline in revenue in the first quarter, primarily due to reduced sales of COVID antibodies.

However, by the fourth quarter, Eli Lilly demonstrated a substantial year-over-year increase, indicative of the sector's transition from pandemic-driven demand to the growing market for metabolism-regulating drugs. According to TD Cowen, sales of Type 2 diabetes and obesity treatments may reach $152 billion by 2030.

Eli Lilly Warns of Temporary Short Supply of Two Insulin Products

CNN Health reported:

Drugmaker Eli Lilly warned this week that two of its formulations of insulin would be temporarily out of stock through the beginning of April, citing a "brief delay in manufacturing."

The 10-milliliter vials of Humalog and insulin lispro injection will be in short supply at wholesalers and some pharmacies, Lilly said in a statement posted online Wednesday. The company said that prefilled pen versions of those medicines are still available in the U.S. and that it continues to manufacture the 10-milliliter vials "and will ship them as soon as we can."

More than 8 million people in the U.S. rely on insulin to survive, according to the American Diabetes Association. Although other forms are available, it's not always simple for patients to switch between different brands of insulin or delivery methods, said Laura Marston, an advocate for lower insulin prices who has type 1 diabetes and uses Humalog.

New Monoclonal Authorized to Prevent COVID in Immunocompromised People — No Such Option Has Been Available Since FDA Revoked the Authorization of Evusheld Last Year

MedPage Today reported:

The FDA issued an emergency use authorization (EUA) for pemivibart (Pemgarda) as COVID-19 pre-exposure prophylaxis in immunocompromised individuals who are unlikely to mount a sufficient immune response following vaccination, the agency announced on Friday.

A long-acting monoclonal antibody, pemivibart is specifically authorized for people ages 12 years and older (and weighing 40 kg or more) with moderate-to-severe immune compromise either because of a medical condition or due to immunosuppressant medications.

Pemivibart is given as a single intravenous infusion and is not for use as post-exposure prophylaxis or in people currently infected with SARS-CoV-2.

FDA cautioned that anaphylaxis occurred in 0.6% of clinical trial participants who received pemivibart. Therefore, patients should be monitored for 2 hours after the infusion is finished, and pemivibart should be administered in settings where health providers have immediate access to medications to reverse severe allergic reactions and can alert EMS if necessary.

Other potential side effects noted in the labeling include infusion-related reactions, fatigue, nausea, and headache.

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And how many babies will die because their parents cannot afford 4.25 million for this "treatment"? These drug pushers are sick, sick puppies.
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a month ago
But you know that pharma does not give a toss about people's health.
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